REMARKS

Objections

The Examiner has objected to claim 124 for a typographical error. Claim 124 has been canceled thus obviating this objection.

The Examiner has objected to the drawings because they do not include figure numbering on the actual drawings. Replacement drawings with proper numbering are attached to this response thus obviating this objection.

The Examiner has objected to the specification as it does not include a proper header above the description of the drawings. The specification has been amended to include this header thus obviating this objection.

35 U.S.C. § 112, second paragraph rejections

Claims 85 and 124 are currently pending in the application. The Examiner has rejected claim 85 under 35 U.S.C. § 112, second paragraph, as being indefinite for the inclusion of broad language in the claim. Claims 85 and 124 have been canceled thus obviating this rejection. Furthermore, new claims 125-127 are directed to a defined compound only and thus this rejection would also not be applicable to claims 125-127.

35 U.S.C. § 112, first paragraph rejections

The Examiner has rejected claim 85 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claims 85 and 124 have been canceled thus obviating this rejection. Furthermore, new claims 125-127 are directed to a defined compound. This compound (numbered 352 in the specification) is disclosed in various parts of the specification (see for example pp. 43, 59), thus satisfying the written description requirement. Furthermore, claims 125-127 are not directed to mimics of the claimed compound, nor are they directed to synthesis of the claimed compound. Thus, those aspects of this rejection are also not applicable to claims 125-127. Written description support for the subject matter of claim 126 can be found in the specification on page 44, para. 2. Written description support for the subject matter of claim 127 can be found in the specification on page 44, para. 2.

35 U.S.C. § 102(b) rejection

The Examiner has rejected claim 85 under 35 U.S.C. § 102(b) as being anticipated by Kawai (U.S. Patent No. 5,387,671). Claim 85 has been canceled thus obviating this rejection. In addition, the compound claimed in new claim 125 is not disclosed in Kawai and thus this rejection is not applicable to claim 125.

35 U.S.C. § 103(a) rejections

The Examiner has rejected claims 85 and 124 under 35 U.S.C. § 103(a) as being obvious over Kawai. Kawai does not teach an embodiment or specific example of the elected species. However, the Examiner argues that the examples in Kawai, when considered as a whole, render the compounds of claims 85 and 124 obvious and that the elected species falls within the genus of claim 1 of Kawai. The fact that the elected species, which is also the subject of new claim 125, may fall within a genus disclosed in the prior art, does not per se render that species obvious over the prior art. Kawai teaches that a polar and charged arginine group is required to be present to achieve significant antagonistic activity. In contrast, the compound of claim 125 is characterized by the presence of a hydrophobic side chain on its terminal part which, in contrast to Kawai examples 170 and 171, provides for an effective C5a antagonist have an IC50 value of less than 200 nM. Furthermore, of the 20 peptides described in WO 9212168 along with their IC50 values (for binding to C5aR), 19 feature a terminal arginine. The peptides containing arginine are reported to have a binding activity of as low as 0.014 μM (Kawai, Table 1). Only one peptide holds a C-terminal phenylbutanoyl residue which could interact via hydrophobic interactions. This peptide (Kawai, example 170), however, is reported to have an IC50 value of only 2.6 μM which, according to Applicant's definition, is insufficient for use as a drug. Had Kawai, who is one of skill in the art, recognized that the presence of hydrophobic C-termini produced high affinity compounds, they would have made and tested more of them. Finally, the IC50 values indicated in WO9212168 are derived from measurements with isolated PMN membranes. Typically, the affinity of compounds to receptors on whole cells, which is a more relevant parameter, is significantly lower (see Kawai et al., 1991 Journal of Medicinal Chemistry 34: 2068-71).

The Applicant has performed testing comparing the compound of Kawai example 171 and the compound of claim 125 in a C5a receptor antagonist activity assay. The results are shown in the attached Rule 132 Declaration. The compound of Kawai example 171 has an activity in a functional assay of > 19 μM, whereas the compound of claim 125 has an activity of 0.039 μM in the same assay. Based on the low activity of the Kawai compounds, one of skill in the art would not be motivated to derive compounds with a phenylalanine substituent as in the present claims. Therefore, the compound of claim 125 is not obvious to one of skill in the art, and this rejection should be withdrawn.

Restriction Requirement

In view of the fact that the claims are now restricted to a single active agent, Applicant requests that the restriction requirement be removed and the pending non-elected claims be rejoined.

Double Patenting rejection

The Examiner has rejected claims 85 and 124 under 35 U.S.C. § 101 for double patenting as being unpatentable over claims 24, 44 of co-pending Application No. 11/814,050. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented. The Applicant requests that this rejection be held in abeyance, to whatever degree it would be applicable to new claim 125, until one of the cases issues.

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the pending claims are requested. The Director is authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

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